Complete Summary

GUIDELINE TITLE

Asthma.

BIBLIOGRAPHIC SOURCE(S)

University of Michigan Health System. Asthma. Ann Arbor (MI): University of Michigan Health System; 2004 Sep. 15 p.

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: University of Michigan Health System. UMHS asthma guideline. Ann Arbor (MI): University of Michigan Health System; 2000 Jan. 14 p.

COMPLETE SUMMARY CONTENT

SCOPE

METHODOLOGY - including Rating Scheme and Cost Analysis
RECOMMENDATIONS
EVIDENCE SUPPORTING THE RECOMMENDATIONS
BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS
QUALIFYING STATEMENTS
IMPLEMENTATION OF THE GUIDELINE
INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT
CATEGORIES

IDENTIFYING INFORMATION AND AVAILABILITY

SCOPE

DISEASE/CONDITION(S)

Asthma

GUIDELINE CATEGORY

Diagnosis Evaluation Management

CLINICAL SPECIALTY

Allergy and Immunology Critical Care Emergency Medicine Family Practice Internal Medicine Nursing Pediatrics Pharmacology Pulmonary Medicine

INTENDED USERS

Advanced Practice Nurses Nurses Pharmacists Physician Assistants Physicians Respiratory Care Practitioners

GUIDELINE OBJECTIVE(S)

To improve the patient's quality of life by achieving and maintaining control of symptoms; attaining normal lung function; minimizing need for as-needed beta2-agonists; avoiding adverse effects from asthma medications; preventing exacerbations; attaining normal activity levels, including exercise; and preventing emergency visits and hospitalizations

TARGET POPULATION

Children, adolescents, and adults with asthma

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis

- 1. Physical examination and patient history (to determine if symptoms and signs of asthma are present)
- 2. Objective measurements of airway obstruction (spirometry)
- 3. Exclusion of alternative diagnoses

Management

- 1. Education of patients to develop a partnership in asthma management
- 2. Assessment of asthma severity with objective measures of lung function (peak expiratory flow rate [PEFR] monitoring)
- 3. Avoidance or control of asthma triggers:
 - Indoor allergens (domestic mites, animal allergens, cockroach allergens, fungi, occupational allergens and irritants)
 - Outdoor allergens (pollens, molds)
 - Food triggers (sulfites, tartrazine [yellow dye], parabens, monosodium glutamate)

- Indoor air pollution (tobacco or other smoke, air pollutants)
- Medications (aspirin, nonsteroidal anti-inflammatory drugs [NSAIDs], beta-blockers)
- Exercise
- Concurrent medical conditions (infections [e.g., viral upper respiratory infection, bronchitis, sinusitis], allergic rhinitis, gastroesophageal reflux disease)
- 4. Establishment of medication plans for chronic management
 - Anti-inflammatory medications:
 - Inhaled corticosteroids: Beclomethasone, metered dose inhaler (MDI) (Qvar [HFA]); Budesonide, dry powder inhaler (DPI) (Pulmicort Turbuhaler); Budesonide (nebulizer solution) (Pulmicort Respules); Triamcinolone, MDI (Azmacort); Flunisolide, MDI (Aerobid); Fluticasone, MDI (Flovent); Salmeterol/fluticasone, DPI (Advair Diskus)
 - Systemic corticosteroids: Prednisone, Prednisolone, Methylprednisolone
 - Leukotriene modifier agents: Montelukast (Singulair), Zafirlukast (Accolate), Zileuton (Zyflo)
 - Non-steroidal drugs with anti-inflammatory properties (mast cell stabilizers): Nedocromil sodium, MDI (Tilade); Cromolyn sodium, MDI (Intal)
 - Bronchodilator medications:
 - Inhaled, short-acting beta2-agonists: Albuterol, MDI (Proventil, Ventolin, Proventil HFA); Pirbuterol, MDI (Maxair Autohaler)
 - Inhaled, long-acting beta2-agonists: Salmeterol, DPI (Serevent Diskus); Formoterol, DPI (Foradil Aerolizer)
 - Methylxanthines: Theophylline (e.g., Theodor, Uniphyl)
 - Anticholinergics: Ipratropium, MDI (Atrovent); Tiotropium, DPI (Spiriva) (Note: The benefits of daily use of anticholinergics for asthma in children and adults have not been established, even though they are commonly used for refractory patients.)
 - Use of bronchodilators: pediatric considerations and home nebulizers
- 5. Establishment of plans for managing exacerbations
 - Drugs for acute exacerbations of asthma in children
 - Albuterol (MDI and nebulizer solution)
 - Levalbuterol (nebulizer solution)
 - Epinephrine HCI (systemic)
 - Ipratropium Bromide (nebulizer solution)
 - Corticosteroids (Prednisone, Prednisolone, Methylprednisolone)
- 6. Regular follow-up care and consideration of consultation or referral

MAJOR OUTCOMES CONSIDERED

- Symptom relief
- Patient quality of life
- Drug interactions and side effects
- Asthma associated morbidity and mortality
- Peak expiratory flow rate (PEFR)
- Occurrence of rescue beta-agonist use

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources) Hand-searches of Published Literature (Secondary Sources) Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The guideline developers identified relevant data via a Medline search that included the following terms: asthma, peak flow meter, spirometry, diagnosis, treatment, randomized controlled trials, practice guidelines. Also reviewed were literature referenced in the National Asthma Education Program's Executive summary: Guidelines for the diagnosis and management of asthma, 1994, and the international consensus report on diagnosis and treatment of asthma: A call to action for US practitioners, Clinical Therapeutics 1994;16(4):694-706.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence for the Most Significant Recommendations

- A. Randomized controlled trials
- B. Controlled trials, no randomization
- C. Decision analysis
- D. Opinion of expert panel

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Quantitative consideration of benefits, harms, costs, and patient preferences

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

University of Michigan Health System (UMHS) guidelines are reviewed by leadership in departments to which the content is most relevant. Guidelines are approved by the Executive Committee of Clinical Affairs (ECCA). The changes in this update were reviewed by members of the following departments: Allergy; Emergency Medicine; Family Medicine; General Internal Medicine; Pediatrics & Communicable Diseases; Pharmacy; Pulmonary & Critical Care Medicine.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Note from the National Guideline Clearinghouse (NGC): The following key points summarize the content of the guideline. Refer to the full text for additional information, including detailed information on diagnosis, six-part asthma management program, dosing and cost of drugs as well as charts for predicted average peak expiratory flows.

The levels of evidence [A-D] are defined at the end of the Major Recommendations.

- A high index of suspicion for asthma is essential. A history of both symptoms and symptom triggers should be obtained. [C]
- Objective evaluation of airflow obstruction is key to the diagnosis, classification, and management of the disease. Goals of treatment should include not only symptomatic relief, but normalization of lung function. [C]
- Therapy should focus on long-term suppressive therapy. Antiinflammatory agents (in particular inhaled corticosteroids) are the cornerstone of therapy for moderately and severely affected patients. Inhaled beta2-agonists should represent "rescue" agents in most instances. [B]
- Patient education should emphasize how to identify and avoid environmental triggers of asthma and smoking cessation. Patients with moderate or severe asthma should be able to measure their peak expiratory flow rate (PEFR) at home and modify their therapy or seek help based on

their performance relative to their personal best peak flow value. Self-management is fundamental to successful therapy. [A]

Definitions:

Levels of Evidence for the Most Significant Recommendations

- A. Randomized controlled trials
- B. Controlled trials, no randomization
- C. Decision analysis
- D. Opinion of expert panel

CLINICAL ALGORITHM(S)

An algorithm is provided in the original guideline document for the management of asthma.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence for each recommendation is given in brackets following the recommendation (see "Major Recommendations).

Conclusions were based on prospective randomized clinical trials (RCTs) if available, to the exclusion of other data; if RCTs were not available, observational studies were admitted to consideration. If no such data were available for a given link in the problem formulation, expert opinion was used to estimate effect size.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Patients with asthma gain symptomatic relief and functional benefit from several classes of anti-inflammatory and bronchodilator medications and from education in self-management of the disease.

Subgroups Most Likely to Benefit

- For patients experiencing difficulty with traditional MDI (Metered Dose Inhaler) technique, other beta2-agonist options include use of the Autoinhaler (breath-activated MDI) and Diskus (breath activated dry powder inhaler).
- Patients who chronically do not adhere to their treatment regimen may benefit from an intensive asthma health behavior/health education intervention.
- African-Americans have asthma-related mortality rates that are higher than Caucasians´ rates.

POTENTIAL HARMS

Side Effects Associated with Pharmacotherapy

- Anti-inflammatory agents
 - Inhaled corticosteroids
 - There is a dose-dependent reduction of short-term growth with the use of conventional doses of beclomethasone dipropionate.
 - Inhaled corticosteroids in doses as high as 800 micrograms per day exert much less short-term growth suppression than lowdose oral corticosteroids.
 - High doses of inhaled corticosteroids may cause systemic side effects (though to a much lesser extent than oral steroids will). Risk of side effects with high-dose inhaled steroids can be minimized by having the patient rinse his/her mouth immediately after inhalation and before swallowing and by using a spacer device.
 - Systemic corticosteroids
 - Chronic systemic corticosteroid therapy may be associated with obesity, moon facies, supraclavicular and nuchal fat pads, striae, easy bruisability, weakness, hypertension, and glucose intolerance.
 - Long-term (>2 weeks) corticosteroid therapy may cause suppression of the hypothalamic-pituitary-adrenal axis. Full recovery of the axis can take up to 12 months depending on the dose, frequency, and duration of antecedent therapy. Symptoms and signs of secondary adrenal insufficiency include weakness, weight loss, and gastrointestinal discomfort. Adrenal insufficiency can evolve into acute adrenal crisis precipitated by severe infection, trauma, or surgery.
 - Systemic corticosteroid therapy can cause osteopenia.
 - Leukotriene modifier agents
 - The U.S. Food and Drug Administration (FDA) mandates monitoring hepatic enzymes with use of the 5-lipoxygenase-inhibitor zileuton.
 - Churg-Strauss Vasculitis has rarely been reported in association with montelukast or zafirlukast in patients tapering chronic systemic corticosteroids.
- Inhaled, short-acting beta2-agonists
 - Several epidemiologic studies have found an association between excess use of beta2-agonist inhalers and asthma mortality. A causal relationship has not been demonstrated, and it is possible that beta2-agonists represent a mere marker for the severity of disease, being more frequently prescribed for patients with life-threatening asthma. If beta2-agonists do have a causative role, it may be an indirect one, such as delaying presentation until airway obstruction is more severe.
 - Increasing reliance on inhaled Beta2-agonists is a marker of worsening disease or an impending severe attack and should trigger an overall reassessment and possible alteration in therapy, usually involving increased efforts to control airway inflammation.

Drug Interactions

Leukotriene modifier agents: Both zafirlukast and zileuton can potentiate warfarin and theophylline as well as interact with several other medications.

Subgroups Most Likely to be Harmed

- Anti-inflammatory agents
 - Long-term linear growth does not appear to be affected by moderate doses (400–800 mcg/day) of inhaled corticosteroids, except in prepubertal males.
 - Children may exhibit growth failure from chronic systemic corticosteroid therapy.
 - In pregnancy, both leukotriene receptor antagonists zafirlukast and montelukast are category B while zileuton is category C.
- Beta2-agonists: Safety and efficacy of the inhaled, long-acting beta2-agonist salmeterol has not been established in children less than 12 years of age.

QUALIFYING STATEMENTS

OUALIFYING STATEMENTS

These guidelines should not be construed as including all proper methods of care or excluding other acceptable methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding any specific clinical procedure or treatment must be made by the physician in light of the circumstances presented by the patient.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Clinical Algorithm

For information about <u>availability</u>, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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ADAPTATION

This guideline was adapted from the National Heart, Lung, and Blood Institute "Expert panel report 2: guidelines for the diagnosis and management of asthma". Bethesda (MD): U.S. Department of Health and Human Services, Public Health Service, National Institutes of Health, National Heart, Lung and Blood Institute; 1997 Jul.

DATE RELEASED

1996 Dec (revised 2004 Sep)

GUIDELINE DEVELOPER(S)

University of Michigan Health System - Academic Institution

SOURCE(S) OF FUNDING

Internal funding for University of Michigan Health System (UMHS) guidelines is provided by the Office of Clinical Affairs. No external funds are used.

GUIDELINE COMMITTEE

Asthma Guideline Team

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Team Leader: Lee Green, MD MPH, Family Medicine

Team Members: James L. Baldwin, MD, Allergy; Cary E. Johnson, PharmD, College of Pharmacy; Cyril M. Grum, MD, Pulmonary & Critical Care Medicine; Martin E. Hurwitz, MD, Pediatrics & Communicable Diseases; F. John Brinley, MD, General Internal Medicine; John G. Younger, MD, Emergency Medicine

Guidelines Oversight Team: Connie J. Standiford, MD; Lee A. Green, MD, MPH; R. Van Harrison, PhD

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

The University of Michigan Health System endorses the Guidelines of the Association of American Medical Colleges and the Standards of the Accreditation Council for Continuing Medical Education that the individuals who present educational activities disclose significant relationships with commercial companies

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Team Member Company/Relationship

James L. Baldwin, MD (none)

F. John Brinley, MD (none)

Cary E. Johnson, PharmD (none)

Lee A. Green, MD, MPH (none)

Cyril M. Grum, MD (none)

Martin E. Hurwitz, MD Merck/Speakers bureau, clinical studies

Glaxo Smith Kline/Speakers bureau, clinical studies

Astra Zeneca/Clinical studies

Pfizer/Speakers bureau, clinical studies

John G. Younger, MD (none)

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GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the <u>University of Michigan Health System Web site</u>.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on August 21, 2000. The information was verified by the guideline developer on November 22, 2000. This NGC summary

was updated on November 8, 2004. The updated information was verified by the guideline developer on December 7, 2004.

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Date Modified: 4/25/2005



